DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0548]

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Determination That DECADRON–LA (Dexamethasone Acetate Injection), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DECADRON–LA (dexamethasone acetate injection), 8 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. As a result of this determination, FDA may approve abbreviated new drug applications (ANDAs) for dexamethasone acetate injection, 8 mg/mL.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs

do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. If the agency determines that a listed drug was withdrawn for reasons of safety or effectiveness, the drug must be removed from the list of approved drug products, and ANDAs referencing that drug may not be approved (§ 314.162).

DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, is the subject of approved NDA 16–675 held by Merck. In a letter to the agency dated June 25, 2002, Merck requested that NDA 16–675 be withdrawn because the drug is no longer marketed. Merck noted that the NDA was not withdrawn because of safety reasons. On December 5, 2003, Gray Cary submitted a citizen petition (Docket No. 2003P–0548/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether DECADRON–LA (dexamethasone acetate

injection), 8 mg/mL, NDA 16–675, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports associated with this drug and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug

products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, may be approved by the agency.

Dated: 8/13/04

August 13, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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